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GRANT NUMBER: DAMD17-94-J-4378

TITLE: The Effects of Brief Psychotherapy on Coping with
Breast Cancer

PRINCIPAL INVESTIGATOR: Kevin D. McCaul, Ph.D.

CONTRACTING ORGANIZATION: North Dakota State University
Fargo, North Dakota 58105-5790

REPORT DATE: October 1996

TYPE OF REPORT: Annual

PREPARED FOR: Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Frederick, MD 21702-5012

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19970314 081

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY (Leave blank)		2. REPORT DATE October 1996	3. REPORT TYPE AND DATES COVERED Annual (1 Oct 95 - 30 Sep 96)	
4. TITLE AND SUBTITLE The Effects of Brief Psychotherapy on Coping with Breast Cancer			5. FUNDING NUMBERS DAMD17-94-J-4378	
6. AUTHOR(S) Kevin D. McCaul, Ph.D.				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) North Dakota State University Fargo, North Dakota 58105-5790			8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) Commander U.S. Army Medical Research and Materiel Command, Fort Detrick, Frederick, MD 21702-5012			10. SPONSORING/MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release; distribution unlimited			12b. DISTRIBUTION CODE	
13. ABSTRACT (Maximum 200 words) The purpose of this study was to test an intervention designed to facilitate the coping efforts of women diagnosed with Stage I or Stage II breast cancer. Our novel approach tested the effects of <i>brief</i> psychotherapy provided by phone. The final sample included 61 women newly diagnosed with breast cancer who were randomly assigned to either the phone treatment or a "standard treatment" condition. Treatment participants received ten therapy phone contacts with psychology graduate students. Therapy focused on cognitive-behavioral treatment and occurred weekly for 1 month and then every-other-week for the next 3 months. Distress and quality of life measures were collected at pretest, after treatment, and at a 10-month follow-up. The best predictor of distress was coping style: Women who reported more avoidant coping were more distressed. In general, treatment women were satisfied with therapy and felt that they could openly discuss important issues. Therapy outcome data immediately following treatment showed no advantage for quality of life outcomes. Treatment women did report improvements in terms of distress, but they were not significantly better than control participants. Phone therapy is acceptable, but it may not be powerful enough to strongly influence important outcomes.				
14. SUBJECT TERMS Breast Cancer			15. NUMBER OF PAGES 14	
			16. PRICE CODE	
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited	

FOREWORD

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Kevin D. McLaugh
PI - Signature

10/30/96
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The Effects of Brief Psychotherapy on Coping with Breast Cancer

INTRODUCTION

Background

It is well known, and hardly surprising, that many women with breast cancer suffer, both physically and psychologically. Recent treatments have succeeded in increasing life expectancy for many women after diagnosis, but life with cancer often includes psychological difficulties that extend to one's family and persist without intervention (Anderson, 1992).

Fortunately, several studies have shown that psychotherapy (in the broadest sense) reduces suffering and can increase longevity. Perhaps the best known of these studies was conducted by Spiegel and his colleagues (Spiegel & Bloom, 1983; Spiegel et al., 1989). In that study, women with metastatic breast cancer met in a weekly support group over a one-year period. Compared to standard treatment control patients, treatment participants showed lessened pain and a better survival rate. We should note that researchers do not always find a relationship between psychological factors and survival per se. However, the relationship between psychotherapy and quality of life is more convincing, and it is the latter outcome that was of primary interest in this pilot study.

We propose that brief, and thus less expensive, treatment may prove beneficial for improving the quality of life for breast cancer patients. As far as we are aware, there are no experimental trials testing this hypothesis, and this study represents a pilot study to test the value of such an approach.

One advantage of brief therapy is that it provides the opportunity for a therapist to interact with a patient over the phone. Such contact may be particularly important, because it can provide access to care for individuals from rural areas. Rural patients often have problems accessing health care, partly because of the inadequate supply of primary care physicians (U.S. Congress, 1990). Brief, weekly phone contacts, can provide psychotherapy access to women from rural areas.

In summary, previous research suggests that supportive psychotherapy can facilitate coping for women with breast cancer. In addition, brief support can be provided over the phone, thus providing access to women from rural areas of the state. In this research, we studied the effectiveness of treatment in a pilot experiment, with women randomly assigned to a psychotherapy treatment or to a no treatment (i.e., standard treatment) condition. We measured coping, psychological distress, and quality of life.

Purpose

This pilot study was intended to provide preliminary data evaluating an intervention designed to help women cope with Stage I or Stage II breast cancer. Our approach is novel because we are testing the effects of *brief* psychotherapy provided by phone. Thus, we can reach patients from rural areas who have difficulty accessing care.

Design

We recruited over 60 women newly diagnosed with Stage I or Stage II breast cancer, and randomly assigned those women in equal numbers to either a treatment or no-treatment (i.e., "standard treatment") condition. Following a baseline assessment, treatment participants received ten therapy phone contacts with psychology graduate students providing the therapy. Therapy was provided weekly for one month and every-other-week for the subsequent three months. Following treatment initiation, we gathered measures 1 month, 4 months, and 10 months later. Assessment included measures of coping, distress, and quality of life.

BODY

Participants

We initially recruited 69 patients to participate, and 56 have completed (or will complete) the study through the 10-month follow-up. Eight of the drop-outs stopped participating at the pretest stage; only five dropped out once the study proper began. Recruitment proceeded as follows: Women newly diagnosed with Stage I or Stage II breast cancer were identified by medical staff or tumor registry, typically at the Roger Maris Cancer Center. Recruitment was also facilitated by medical staff who informed women about the study when they were in the Cancer Center for medical care. Satellite clinics provided some referrals from regional locations.

After women were identified, we typically contacted them by telephone. The purpose of the study was explained and information was provided about informed consent. Once women agreed to participate, they completed baseline measures (either at home or in the clinic), and telephone therapy began the week following return of the questionnaires.

We present data in this final report based on 61 women. Our original statement of work stated that we would recruit 60 women, so were successful in this part of the study. Because recruitment and treatment went so well, medical staff encouraged

us to admit women with more advanced breast cancer, but we did not receive supplementary support to augment this study for such participants. Although all of our participants have now completed the treatment phase of the study, we will not complete 10-month follow-up data collection for about another month. Thus, the treatment outcome analyses presented in this report are based on only the 4-month (immediately post-treatment) follow-up data. We will present the analyses based on our complete sample and long-term follow-up next fall at the Proceedings of the Breast Cancer Research Program.

Of the final 61 participants, 30 were diagnosed with Stage I, 28 with Stage II, and 3 with Stage III breast cancer. All participants are Caucasian with the exception of one Native American. Nearly all (83%) of the participants had completed high school, and 35% had completed a college education. More than half (68%) were married and nearly half (44%) worked full-time outside of the home.

Treatment

As originally planned, we contacted experimental participants ten times. The initial calls, which were once/weekly, focused on obtaining general information regarding the participant's experiences regarding diagnosis and treatment. In subsequent calls, we explored in more depth the participant's beliefs, thoughts, and emotions, in order to provide support and facilitate problem solving. Participants were regularly asked about their mood and anxiety, and relaxation/worry reduction techniques were frequently taught. The content of calls varied as necessary to meet the participant's needs, ranging from discussion of recent activities (e.g., vacations) to facing thoughts of death and dying. Our treatment outcome manuscript, which will not be completed until Spring, 1997, will include a data-based summary of the content of treatment.

The telephone calls were placed by the therapist at a mutually agreed upon date and time. The length of calls was about 30 minutes. Although the calls were scheduled in advance, therapists frequently found that they had to be flexible about rescheduling the telephone session because of participants' needs (e.g., feeling unwell, children to look after, unexpected guests). When this occurred, the call was rescheduled within a week. For therapist supervision and therapy process analysis, some of the telephone sessions were audiotaped with the participant's consent.

Measures

We gathered several background variables that could predict distress. Demographic variables included age, marital status, working outside the home, and education. Medical variables included cancer stage (I vs. II and III), treatment

(lumpectomy vs. modified radical mastectomy), and type of adjuvant treatment (none vs. chemo only vs. radiation or chemo + radiation). Available social support was measured by asking participants who was available for emotional support—who they could talk to when having problems. Response categories included spouse, parent, child, sibling, a friend, and “other”. We summed across these sources of support to create a total number of support opportunities.

Coping was measured using the Coping Response Indices (R), a measure that provides three measures of coping style: active cognitive coping, active behavioral coping, and avoidance coping (Moos, Cronkite, Billings, & Finney, 1983). Participants completed the measure for how they were coping with the stress of cancer rather than their “typical” style. Internal consistency for the subscales (alpha coefficient) ranged from .43 (avoidance) to .53 (active cognitive) to .76 (active behavioral).

Distress was measured with the Profile of Mood States (POMS; McNair, Lorr, & Droppleman, 1971). Participants complete the inventory for their feelings during the previous week. The scale assesses the intensity of six moods: anxiety, depression, vigor, fatigue, anger, and confusion. Internal consistency ranged from .63 (confusion) to .93 (fatigue), with an average across the six subscales of .80.

Quality of Life was measured using the Medical Outcomes Scale (MOS) short-form (Stewart, Hays, & Ware, 1988). This 20-item scale represents six concepts: physical, role, and social functioning, and mental health, health perceptions, and pain. Internal consistency ranged from .70 (physical functioning) to .84 (mental functioning), with an average across the subscales of .74.

Results

We present the results in three sections. First, we address how baseline (pretest) measures predict distress. These data are important, because they tell us which women may be most at risk for negative outcomes resulting from diagnosis and treatment. Second, we present a preliminary description of our therapy outcome data. Finally, we describe participants’ reactions to phone therapy.

Predicting Distress. For the background variables, we either computed correlations (e.g., for age) or performed analyses of variance (e.g., for disease stage), using the individual MOS and POMS scores as the outcome variables. These analyses were done separately for the cross-sectional data collected at baseline and prospectively, predicting the 4-month outcomes from baseline assessment. In general, these analyses sometimes revealed significant associations at pretest. But there was little consistency across dependent measures, and the reliable associations typically disappeared at the 4-month

follow-up. The following list summarizes these analyses for each of the background predictors.

- ▶ We computed 31 correlations between age and the outcome measures, and only two were significant. Younger age predicted poorer mental health at 4 months on the MOS but less fatigue on the POMS.
- ▶ ANOVAS were used to compare women who were married ($n = 48$) versus those who were not ($n = 13$). In general, the means for these comparisons showed that married women reported a poorer quality of life. Significant differences were obtained concurrently (at baseline) for physical functioning, mental functioning, pain, reported stress, and fatigue. A similar pattern of means was evident predicting the 4-month outcomes, but none of the differences were significant at that time.
- ▶ We compared women who worked outside the home versus those who did not, using t tests. No reliable differences appeared at either time period.
- ▶ More education was related to poorer functioning at baseline on two MOS measures: pain and social functioning. These correlations were not significant at 4-months.
- ▶ ANOVAS were used to compare women who were diagnosed with either Stage I ($n = 30$) or Stages II and III ($n = 31$). The means for these two groups of women were similar--there was no hint that women with a more severe diagnosis were experiencing a poorer quality of life or more distress. Indeed, the only significant differences showed just the reverse: Women diagnosed with Stage I cancer reported *more* confusion and *higher* levels of avoidant coping than women with Stage II/III cancer. The avoidant coping difference was maintained at 4 months.
- ▶ ANOVAs comparing cancer treatments (lumpectomy vs. modified radical mastectomy) showed no trend that the more severe treatment produced a poorer quality of life, and there were no significant differences at either time period.
- ▶ ANOVAs were used to compare the three adjuvant treatments (none vs. chemo only vs. radiation or chemo + radiation); the analyses showed no significant differences.
- ▶ Available social support was related concurrently to 3/6 MOS outcomes and none of the POMS variables. Interestingly, more available social

support was related to *lower* quality of life ($r_s = -.37$ with physical functioning, $-.27$ with role functioning, and $-.32$ with pain). Prospectively, available social support predicted two MOS outcomes, again in the counter-intuitive direction. More available social support was related to poorer physical functioning and more fatigue.

It is reasonable to conclude that the background variables we collected were not good predictors of either quality of life or psychological distress. However, one variable--avoidant coping--did prove to show some prospective power.

Table 1 presents correlation coefficients, using the three coping scales to predict distress and quality of life at baseline (cross-sectional) and prospectively over 4 months. As the table shows, only avoidance coping was consistently related to quality of life. The negative relationships indicate that a greater use of avoidance coping was associated with poorer quality of life--these relationships were significant for four of six scales concurrently, though none prospectively. No coping-quality of life relationships were significant for the active methods of coping.

Table 1
Correlations Between Coping and Outcome Measures

	Coping--Cross-Sectional			Coping--Prospective		
	Behavioral	Cognitive	Avoidance	Behavioral	Cognitive	Avoidance
Quality of Life Outcome						
Physical	--	--	-.26	--	--	--
Role	--	--	-.42	--	--	--
Social	--	--	-.49	--	--	--
Mental	--	--	-.50	--	--	--
Health	--	--	--	--	--	--
Pain	--	--	--	--	--	--
Profile of Mood States						
Anger	--	--	.62	--	--	.52
Depression	.27	--	.57	--	--	.47
Fatigue	--	--	.52	--	--	.46
Active	--	--	-.30	.30	--	--
Anxiety	.33	.30	.44	--	--	--
Confusion	--	--	--	--	--	.38

Note. Only significant ($p < .05$, two-tailed) correlations are included in the table.

Avoidant coping was even a stronger predictor of psychological distress. Greater avoidance coping predicted greater distress both cross-sectionally and

prospectively. Interestingly, the few reliable correlations with active coping were in the same direction--greater coping was associated with more distress.

Therapy Outcome. Table 2 presents the means for quality of life and distress by condition and across a 4-month interval. The data are for 50 women who completed every measure at both time periods. The means prompt several observations, which differ in kind for the quality of life versus distress outcome measures.

1. *Both* control and treatment women reported improvements for each individual quality of life measure. At follow-up, the means for some of these measures are approaching ceiling (which would be a value of 100). Clearly, there are no control-treatment differences for quality of life.
2. At pretest, treatment women reported more distress on the POMS measures than control women. These differences were actually significant for anger [$t(57) = 2.62, p = .011$] and fatigue [$t(57) = 2.10, p = .041$]. By posttest, treatment women showed improvement on every measure of distress, and they were no longer more distressed than control women. In general, then, treatment women showed more improvement than controls. However, it is important to note that we performed analyses of covariance on each of the posttest distress outcomes, using pretest values as the covariate. *None* of the 4-month differences was significant.

Phone Therapy. It is important to ask whether the women receiving phone therapy found it to be acceptable. In general, the answer to this question was "yes". On written scales, women reported that they were able to reveal their true feelings on the phone ($M = 4.58$, with 1 = "never" and 5 = "always") and that they were comfortable talking on the phone ($M = 3.50$, with 1 = very uncomfortable; 4 = very comfortable).

We also asked several open-ended questions. Only a few women (4/24 or 17%) would have preferred face to face rather than phone contacts. The three most important things women reported receiving were being able to talk out their feelings, hearing how others experienced the disease, and obtaining ideas for how to cope with breast cancer. Finally, when asked what they would change, more than half reported "nothing". Some women would have preferred more frequent contacts, and being able to control the timing of phone contacts.

Table 2
Means for Outcome Variables By Condition Across Time

	Time	Controls (<i>n</i> = 27)		Treatment (<i>n</i> = 23)	
		Pretest	Follow-up	Pretest	Follow-up
Quality of Life					
Physical		60.2	82.4	72.1	73.9
Role		53.7	86.1	57.6	71.7
Social		83.0	85.9	75.7	79.1
Mental		71.7	73.5	68.4	75.3
Health		61.1	66.1	62.4	71.7
Pain		57.4	69.4	57.6	71.7
<hr/>					
	Time	Controls (<i>n</i> = 27)		Treatment (<i>n</i> = 23)	
		Pretest	Follow-up	Pretest	Follow-up
Profile of Mood States					
Anger		4.19	4.77	6.27	5.17
Depression		6.58	5.58	8.34	6.50
Fatigue		9.31	8.90	12.2	9.18
Active		11.8	13.8	11.1	11.8
Anxiety		3.00	3.32	3.20	2.94
Confusion		2.58	2.38	2.86	2.38

Note. Higher numbers indicate better quality of life and higher levels of each mood state. "Follow-up" data are from the 4-month follow-up, which immediately followed the end of phone therapy.

CONCLUSIONS

We offer three important observations derived from the analyses we have conducted thus far.

(1) With one important exception, the background variables we collected at pretest failed to predict quality of life or distress off women with breast cancer. The exception was a measure of avoidant coping. This measure predicted both kinds of outcome measures at pretest and was strongly associated with reported distress at 4 months.

Many of the women in our study did *not* report significant emotional upset or lowered quality of life. Therefore, it would make sense to select for treatment those women who are most likely to need help. We propose that women engaged in significant avoidant coping may be a likely group.

(2) Phone therapy is acceptable to patients.

(3) It is not clear whether brief phone therapy, at least as offered here, is effective. Strong conclusions, however, must await analysis of the long-term follow-up data.

REFERENCES

- Anderson, B.L. (1992). Psychological interventions for cancer patients to enhance the quality of life. *Journal of Consulting and Clinical Psychology*, 60, 552-568.
- McNair, D.M., Lorr, M., & Droppleman, L.F. (1971). *Profile of Mood States*. San Diego, CA: Educational and Industrial Testing Service.
- Moos, R., Cronkite, R., Billings, A., & Finney, J. (1983). *Health and Daily Living Form Manual*. Palo Alto: Social Ecology Laboratory.
- Spiegel, D., & Bloom, J.R. (1983). Group therapy and hypnosis reduce metastatic breast carcinoma pain. *Psychosomatic Medicine*, 45, 333-339.
- Spiegel, D., Bloom, J.R., Kraemer, H.C., & Gottheil, E. (1989). Effect of psychosocial treatment on survival of patients with metastatic breast cancer. *The Lancet*, Oct. 14th, 888-891.
- Stewart, A.L., Hays, R.D., & Ware, J.E. (1988). The MOS short-form general health survey: Reliability and validity in a patient population. *Medical Care*, 26, 724-735.
- U.S. Congress, Office of Technology Assessment (1990). *Health Care in Rural America*, OTA-H-434. Washington, DC: U.S. Government Printing Office.

FINAL REPORT

Bibliography

McCaul, K.D., & Sandgren, A.K. (1996, September). Telephone therapy for breast cancer patients. Paper presented at the First National Conference on Rural Mental Health Research, Grand Forks, ND.

Sandgren, A.K., & McCaul, K.D. (1996, October). Telephone therapy and coping with breast cancer. Paper presented at the 3rd World Congress of Psycho-Oncology, New York.

We are working on three manuscripts to describe the two years of our study.

McCaul, K.D., Sandgren, A.K., King, B., O'Donnell, S., Branstetter, A., & Foreman, G. (in progress). Predicting adjustment to breast cancer. North Dakota State University and the Roger Maris Cancer Center.

Sandgren, A.K., & McCaul, K.D. (in progress). Does phone therapy help breast cancer patients cope with the disease? North Dakota State University and the Roger Maris Cancer Center.

Sandgren, A.K., McCaul, K.D., & Foreman, G. (in progress). A case by case examination of coping with breast cancer: Who adjusts? North Dakota State University and the Roger Maris Cancer Center.

Personnel

Kevin D. McCaul, Ph.D.	co-investigator
Ann K. Sandgren, Ph.D.	co-investigator
Ann Branstetter, M.S.	therapist
Brenda King, M.S.	therapist
Susan O'Donnell, M.S.	therapist
Greg Foreman, B.A.	data analyst